Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1. (original) A method for treating a patient suffering from a cancerous disease comprising:

administering to said patient an anti-cancer antibody or fragment thereof produced in accordance with a method for the production of anti-cancer antibodies which are useful in treating a cancerous disease, said antibody or fragment thereof characterized as being cytotoxic against cells of a cancerous tissue, and being essentially benign to non-cancerous cells;

wherein said antibody or fragment thereof is placed in admixture with a pharmaceutically acceptable adjuvant and is administered in an amount effective to mediate treatment of said cancerous disease;

said antibody being an isolated monoclonal antibody or antigen binding fragment thereof which binds to an antigenic moiety expressed by said cancerous tissue, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone

deposited with the ATCC as PTA-4890.

Claim 2. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 1, wherein said antibody or fragment thereof is humanized or chimerized.

Claim 3. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 comprising:

conjugating said antibody or antigen binding fragment thereof with a member selected from the group consisting of toxins, enzymes, radioactive compounds, and hematogenous cells, thereby forming an antibody conjugate; and

administering antibody conjugate or conjugated fragments thereof to said patient;

wherein said antibody conjugate or conjugated fragments are placed in admixture with a pharmaceutically acceptable adjuvant and are administered in an amount effective to mediate treatment of said cancerous disease.

Claim 4. (withdrawn) The method of claim 3, wherein said antibody or fragment thereof is humanized or chimerized.

Claim 5. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through antibody dependent cellular toxicity.

Claim 6. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through complement dependent cellular toxicity.

Claim 7. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through catalyzing of the hydrolysis of cellular chemical bonds.

Claim 8. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through producing an immune response against putative cancer antigens residing on tumor cells.

Claim 9. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through targeting of cell membrane proteins to interfere with their function.

Claim 10. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through production of a conformational change in a cellular protein effective to produce a signal to initiate cell-killing.

Claim 11. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 1 wherein:

said method of production utilizes a tissue sample containing cancerous and non-cancerous cells obtained from a particular individual.

Claim 12. (original) A method for treating a patient suffering from a cancerous disease comprising:

administering to said patient an antibody or antigen binding fragment thereof produced in accordance with a method for the production of anti-cancer antibodies which are useful in treating a cancerous disease, said antibody being cytotoxic against cells of a cancerous tissue, and essentially benign to non-cancerous cells;

wherein said antibody is the isolated monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890 or an antigen binding fragment thereof, and is placed in admixture with a pharmaceutically acceptable adjuvant and is administered in an amount effective to mediate treatment of said cancerous disease.

Claim 13. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 12, wherein said antibody or fragment thereof is humanized or chimerized.

Claim 14. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 comprising:

conjugating said antibody or fragment thereof with a member selected from the group consisting of toxins, enzymes, radioactive compounds, and hematogenous cells, whereby an antibody conjugate is formed; and

administering said antibody conjugates or fragments thereof to said patient;

wherein said conjugated antibodies are placed in admixture with a pharmaceutically acceptable adjuvant and are administered in an amount effective to mediate treatment of said cancerous disease.

Claim 15. (withdrawn) The method of claim 14, wherein said antibody or fragment thereof is selected from said subset are humanized or chimerized.

Claim 16. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through antibody dependent cellular toxicity.

Claim 17. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through complement dependent cellular toxicity.

Claim 18. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through catalyzing of the hydrolysis of cellular chemical bonds.

Claim 19. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through producing an immune response against putative cancer antigens residing on tumor cells.

Claim 20. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through targeting of cell membrane proteins to interfere with their function.

Claim 21. (withdrawn) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

the cytotoxicity of said antibody or fragment thereof is mediated through production of a conformational change in a cellular protein effective to produce a signal to initiate cell-killing.

Claim 22. (original) The method for treating a patient suffering from a cancerous disease in accordance with claim 12 wherein:

said method of production utilizes a tissue sample containing cancerous and non-cancerous cells obtained from a particular individual.

Claim 23. (original) A process for mediating cytotoxicity of a human tumor cell which expresses a CD63 antigenic moiety on the cell surface comprising:

contacting said tumor cell with an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment thereof which binds to said expressed CD63 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4890, whereby cell cytotoxicity occurs as a result of said binding.

Claim 24. (original) The process of claim 23 wherein said isolated antibody or antigen binding fragments thereof are humanized or chimerized.

Claim 25. (withdrawn) The process of claim 23 wherein said isolated antibody or antigen binding fragments thereof are conjugated with a member selected from the group consisting of cytotoxic moieties, enzymes, radioactive compounds, and hematogenous cells, whereby an antibody conjugate is formed..

Claim 26. (original) The process of claim 23 wherein said isolated antibody or antigen binding fragments thereof are humanized or chimerized.

Claim 27. (original) The process of claim 23 wherein said isolated antibody or antigen binding fragments thereof are murine.

Claim 28. (original) The process of claim 23 wherein the human tumor tissue sample is obtained from a tumor originating in a tissue selected from the group consisting of colon, ovarian, lung, prostate and breast tissue.

Claim 29. (withdrawn) A binding assay to determine a presence of cells which express a CD63 antigenic moiety which specifically binds to an isolated monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890, or an antigen binding fragment thereof comprising:

providing a cell sample;

providing an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment thereof which binds to said expressed CD63 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890;

contacting said isolated monoclonal antibody or antigen binding fragment thereof with said cell sample; and

determining binding of said isolated monoclonal antibody or antigen binding fragment thereof with said cell sample;

whereby the presence of cells which express a CD63 antigenic moiety which specifically binds to said isolated monoclonal antibody or antigen binding fragment thereof is determined.

Claim 30. (withdrawn) The binding assay of claim 29 wherein the cell sample is obtained from a tumor originating in a tissue selected from the group consisting of colon, ovarian, lung, prostate and breast tissue.

Claim 31. (withdrawn) A process of isolating or screening for cells in a sample which express a CD63 antigenic moiety which

specifically binds to an isolated monoclonal antibody or antigen binding fragment thereof, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890 comprising:

providing a cell sample;

providing an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment thereof which binds to said expressed CD63 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890;

contacting said isolated monoclonal antibody or antigen binding fragment thereof with said cell sample; and

determining binding of said isolated monoclonal antibody or antigen binding fragment thereof with said cell sample;

whereby said cells which express a CD63 antigenic moiety which specifically binds to an isolated monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890, or antigen binding fragment thereof are isolated by said binding and their presence in said cell sample is confirmed.

Claim 32. (withdrawn) The process of claim 31 wherein the cell sample is obtained from a tumor originating in a tissue selected from the group consisting of colon, ovarian, lung, prostate and breast tissue.

Claim 33. (withdrawn) A method of extending survival and/or delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended.

Claim 34. (withdrawn) The method of claim 33 wherein said antibody is conjugated to a cytotoxic moiety.

Claim 35. (withdrawn) The method of claim 33 wherein said cytotoxic moiety is a radioactive isotope.

Claim 36. (withdrawn) The method of claim 33 wherein said antibody activates complement.

Claim 37. (withdrawn) The method of claim 33 wherein said antibody mediates antibody dependent cellular cytotoxicity.

Claim 38. (withdrawn) The method of claim 33 wherein said antibody is a murine antibody.

Claim 39. (withdrawn) The method of claim 33 wherein said antibody is a humanized antibody.

Claim 40. (withdrawn) The method of claim 33 wherein said antibody is a chimerized antibody.

Restriction/Election

Restriction to one of the following inventions has been required under 35 USC 121:

I. Claims 1-28, drawn to a method for treating a patient suffering from a cancerous disease comprising: administering to said patient an anti-cancer antibody or fragment; said antibody being an isolated monoclonal antibody or antigen binding fragment thereof which binds to an antigenic moiety expressed by said cancerous tissue, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890, classified in class 424, subclass 141.1.

II. Claims 29-32, drawn to a binding assay to determine a presence of cells which express a CD63 antigenic moiety which specifically binds to an isolated monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890, or antigen binding fragments thereof, classified in class 435, subclass 7.21.

III. Claims 33-40, drawn to a method of extending survival by treating a human tumor in a mammal, wherein said tumor expressed an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby survival is extended, classified in class 424, subclass 141.1.

It is noted for Applicant's convenience that this is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to methods with different objectives which do not share, as a whole, a substantial feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that the unity of invention exists wherein entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Board of

Patent Appeals and Interferences 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEP 803.02.

IV. Claims 33-40, drawn to a method of delaying disease progression by treating a human tumor in a mammal, wherein said tumor expressed an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed, classified in class 424, subclass 141.1.

It is noted for Applicant's convenience that this is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to methods with different objectives which do not share, as a whole, a substantial feature

disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that the unity of invention exists wherein entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Board of Patent Appeals and Interferences 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEP 803.02.

The Examiner has also required the following Species Elections:

Species Election for Group I

A. Claims 1, 12, and 23 are generic to the following disclosed patentably distinct species of antibody:

1) conjugated

2) not conjugated

If Applicant elects species A1 then Applicant must elect a species from B.

B. Claims 1, 12, and 23 are generic to the following disclosed patentably distinct species of conjugates:

1) toxins

2) enzymes

3) radioactive compounds

4) hematogenous cells

C. Claims 1 and 12 are generic to the following disclosed patentably distinct cytotoxicity mediated by the antibody:

1) antibody dependent cellular toxicity

2) complement dependent cellular toxicity

3) catalyzing of the hydrolysis of cellular chemical bonds

4) producing an immune response against putative cancer antigens residing on tumor cells

5) targeting of cell membrane proteins to interfere with their function

6) production of a conformational change in a cellular protein effective to produce a signal to initiate cell-killing

D. Claim 23 is generic to the following disclosed patentably distinct species of tissue of tumor origin:

1) colon

2) ovarian

3) lung

4) prostate

5) breast

E. Claim 23 is generic to the following disclosed patentably distinct species of antibody:

1) murine

2) human

Species Elections for Group II

A. Claims 29 and 31 generic to the following disclosed patentably distinct species of tissue of tumor origin:

1) colon

2) ovarian

3) lung

4) prostate

5) breast

Species Elections for Groups III and IV

A. Claim 33 is generic to the following disclosed patentably distinct species of antibody:

1) conjugated

2) not conjugated

If Applicant elects A1 then Applicant must elect a species from B.

B. Claim 33 is generic to the following disclosed patentably distinct species of conjugates:

1) cytotoxic moiety

2) radioactive isotope

C. Claim 33 is generic to the following disclosed patentably distinct cytotoxicity mediated by the antibody:

1) antibody activates complement

2) antibody mediates antibody dependent cellular cytotoxicity

D. Claim 33 is generic to the following disclosed patentably distinct species of antibody:

1) murine

2) human